

AMENDMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 03/02/92 OUT 07/01/92

Srinivas Gowda
Reviewed by Srinivas Gowda Date 07/01/92
EPA Reg. No. or File Symbol 62401-1
Date Division Received 02-18-91
Type Product General Disinfectant
MRID No (s) 422066-01
Product Manager PM 31 (Lee)
Product Name New Viva Plus Bathroom Disinfectant Cloths
Company Name Nordico, Inc.
Submission Purpose Amendment to add new use-pattern(s), new name,
one-step/re-use food contact surface/non-food
contact surface sanitizing claims with
one-step/re-use non-food contact surface
sanitizing efficacy data and proposed label.
Also, New Quantitative Sanitizing Test Method
for Towelettes
Type Formulation Single Use Disposable impregnated towelette(Dry)
to be wet with water

Active Ingredient (s): %

N-Alkyl (68% C12, 32% C14) Dimethyl
ethyl benzyl ammonium chlorides.....0.475
N-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
Dimethyl benzyl ammonium chlorides.....0.475

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Date Division Received 02-18-91
MRID No (s) 422066-01
Product Manager PM 31 (Lee)
Product Name New Viva Plus Bathroom Disinfectant Cloths
Company Name Nordico, Inc.

Submitted data:

"Report on the Evaluation of the Sanitizing Efficacy Over Time of the Nordico (Dry) Sanitizer Towels (Quix) Against Staphylococcus aureus, Klebsiella pneumoniae and Listeria monocytogenes."

Marypaul Lab. No's: R2689-R2692, by Mary Anne K. La Rocca and Paul T. La Rocca, Marypaul Laboratories, Inc., P.O. Box 952, 70 Sparta Avenue, Sparta, NJ 07871, dated 01-27-92 (MRID No. 422066-01)

Efficacy Not Supported By The Data:

The submitted non-food contact surface sanitizing data are not acceptable to support food-contact surface sanitizing claims. Refer to DIS/TSS-4 enclosure, item (2) which gives the acceptable AOAC procedure for testing of sanitizing rinses for previously cleaned food contact surfaces. (Among other requirements, food contact sanitizing testing has to show a 99.999 % reduction in microbial populations within 30 seconds.) The submitted Sanitizer Test data (for inanimate, non-food contact surfaces) is for substantiating sanitizing claims for non-food contact surfaces such as floor, walls, and furnishing and not for those surfaces which come in contact with food or beverages, such as table, counter tops, appliances, sinks, and stove tops in Eating establishments.

In addition, the test method employed has the following deficiencies (for non-food contact hard surface sanitation purposes):

1. The testing as performed is not suitable for quantitative bacteriological analysis without inclusion of a step for culturing of the fluids in the towelette

at each sampling interval [see Efficacy Data Requirements for Presaturated or Impregnated Towelettes for Hard Surface Disinfection, #1(a)(b)].

2. The "bioburden" employed is not sufficient for re-use on surfaces that are not pre-cleaned. The minimum bioburden load should be approximately equivalent to one glass slide contaminated with at least 10^6 viable bacteria per each 5 ml of use solution used for wetting the towelettes [see Efficacy Data Requirements for Presaturated or Impregnated Towelettes for Hard Surface Disinfection, item #2(a)(i)]. (Also see DIS/TSS-2, item 4: "The effectiveness of the antimicrobial agent must be demonstrated in the presence of a specific organic soil and at appropriate concentration level when specifically claimed and/or indicated by the pattern of use).
3. The water hardness used in the testing was not given. The data should be developed with hard water since the label directions imply use of tap water.
4. The towels were not rinsed in water after each slide wiping step as is required in the use directions.
5. The submitted data do not pass the non-food Sanitizer Test requirements, since the data tables show less than 99.9 % reduction in at 0, 1/2 and 1 hours for all three organisms tested.
6. The submitted data do not document the absence of residual effects of the active ingredients in the subculture medium (neutralization control procedure/data). (See DIS/TSS-2, item #7)
7. **Non-Compliance With Pesticide Assessment Guideline, Subdivision G §91-2(k) & §91-30(c)(1):**

Your data submittal was found to be only partially in compliance with the standards for reporting of data contained in Pesticide Assessment Guideline, Subdivision G §91-2(k) & §91-30(c)(1). The following was missing: How slides were wiped and the number of slides wiped each time; Complete report of results obtained for each individual replication (actual dilution plate counts at various dilutions); Percent Asolectin and Tween in the neutralizer solution; Culture/Subculture medium employed; Chemical Analysis Method.

The title page was not formatted completely in accordance with PR Notice 86-5.

Non-Compliance With Good Laboratory Practice Standards of 40 CFR 160.185:

Your data submittal was found to be only partially in compliance with the standards for reporting of study results contained in 40 CFR 160.185. There is no evidence of compliance with items 4 (identity, strength, purity, and chemical composition of test substances, R2690, R2691, and R2692 to verify if the efficacy data were developed at the lower certified limit and to know if the samples were from a batch of commercial use material or laboratory bench samples manufactured for this specific testing), 7 (including the procedure used for identification of the test organisms, source of supply and date obtained), 10, 12 (including the names of other scientists or professionals involved in the study. The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data from the study after data generation was completed), 13, & 14 (including study inspections dates and final study report review dates). Lack of the above information constitutes non-compliance with the published GLP regulations.

Unacceptable Use Patterns:

The proposed new use patterns are unacceptable because:

1. Preparation of **use-solution** by placing 1 towelette in 16 ounces of water and use and re-use of this solution over a period of eight hours to sanitize soiled, hard, porous and non-porous, food contact and non-food contact surfaces is unacceptable.
2. Claims for a use pattern of "one-step re-use" cleaning and sanitizing are not generally acceptable for food-contact surfaces. Refer to the attached DIS/TSS-17 enclosure, item 3.
3. Formulations not cleared under the Federal Food, Drug, and Cosmetic Act are not acceptable for use on food contact surfaces as a terminal sanitizing rinse. Your formulation does not meet the requirements of 21 CFR 178.1010.
4. EPA has no re-use test protocol specifications applicable to the proposed food-contact efficacy claims and patterns of use. Towelettes are intrinsically not amenable for efficient food contact surface sanitization.

Labeling:

The proposed labeling dated 02-18-92 is not acceptable for the reasons given above.

The following comments are on your last accepted label dated 05-18-90 (New Viva Plus Bathroom Disinfectant Cloths):

The label must identify the major area(s) in which the product is recommended for use (e.g. homes, motels, schools) so as to exclude hospital (medical/dental/veterinary) areas (See DIS/TSS-15 enclosure)

The directions for use must be expanded to include that surfaces must remain wet for at least 10 minutes for disinfection.

The directions for heavily soiled surfaces must be revised to indicate that the surface must first be cleaned with one towelette and then disinfected with a second fresh towelette.

Provide instructions to remove gross filth or heavy soil prior to application of the product.

Identify the type of bathroom surfaces intended for treatment, in addition to description of surface composition (e.g. stainless steel, chrome, glass, vinyl).

Under the heading "To Clean and Disinfect Toilet Surfaces" include instructions to remove residual bowl water prior to application of the product, instructions to remove gross filth or heavy soil prior to application of the product, amount of water to be used to moisten the towelette, and include a statement such as "to wet all surfaces thoroughly including under the rim and let stand at least 10 minutes."

On your "New Viva Plus Kitchen Sanitizing Cloths" label (EPA Reg. No. 62401-2) revise the directions for use to include all the information indicated in items 1, 3, 5, and 6 on the DIS/TSS-15 enclosure. The directions for heavily soiled surfaces must be revised to indicate that the surface must first be cleaned with one towelette and then disinfected with a second fresh towelette. Also, specify the amount of water to be used to moisten the towelette.

Note to PM 31:

Previously accepted Toxicology Studies were not developed on the dry towelette.